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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,899	10/22/2001	Oleg Shikhman	INE-0061	6867

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EXAMINER	
BAXTER, JESSICA R	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,899	SHIKHMAN ET AL.	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *15-54 and 60-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5-8, 10, 12, 13, 14, 55, 56, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,643,289 to Sauer et al.

Sauer discloses a crimping and cutting device comprising a hammer head (26) having a first side and an opposite second side, and a ferrule engaging edge (FIG. 8) located on the second side; a tip having a distal end and a proximal end (16), the tip having a hammer head opening for receiving the hammer head (FIG. 8), the hammer head opening extending from the distal end of the tip to the proximal end of the tip, the tip further having a ferrule accepting opening near the distal end of the tip (FIG. 8 securing member 100), and a generally stationary cutting edge within the hammer head opening, the cutting edge located proximally of the ferrule accepting opening (blade 30), a handle assembly having a trigger (FIG. 1 handle 12), wherein activation of the trigger draws the hammer head proximally within the tip (handle member 48). The device further comprises an adjustment screw within the handle assembly, wherein a length of a central rod connecting the hammer head to the handle assembly is adjustable by the adjustment screw (pin 65), wherein the hammer

head further comprises a first camming surface located on the first side of the hammer head and the tip comprises a second camming surface near the distal end of the tip and opposite the ferrule accepting opening (FIGS 8 and 9), wherein the movement of the hammer head in a proximal direction directs the hammer head towards the ferrule accepting opening (FIG. 9), wherein the first camming surface and the second camming surface abut flushly when the hammer head is at the distal end of the tip, wherein the first camming surface does not abut the second camming surface when the hammer head is pulled proximally of the ferrule accepting opening, wherein the tip further comprises an aperture between the distal end and the proximal end of the tip, the cutting edge located distally of the aperture (FIG. 9).

Sauer discloses a suture loading assembly for threading suture material through a surgical instrument, the suture loading assembly comprising: a body, an attaching member extending from the body for attaching the body to the surgical instrument; and, a flexible loop extending from a distal end of the body (Column 7 lines 1-21).

3. Claims 1-10, 12, 55 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent no. 6,641,592 to Sauer et al.

Regarding claim 1, Sauer discloses a crimping and cutting device comprising: a hammer head (134) having a first side and an opposite second side, and a ferrule engaging edge located on the second side (FIG. 16A); a tip (106) having a distal end and a proximal end, the tip having a hammer head opening for receiving the hammer head (128), the hammer head opening extending from the distal end of the tip to the proximal end of the tip, the tip further having a ferrule accepting opening (138) near the distal end of the tip, and a generally stationary cutting edge within the hammer head opening (144), the cutting edge located proximally of the ferrule accepting opening.

Regarding claim 2, Sauer discloses that the hammer head further comprises a first camming surface (134a) located on the first side of the hammer head and the tip comprises a second camming surface (128a) near the distal end of the tip and opposite the ferrule accepting opening.

Regarding claim 3, Sauer discloses that movement of the hammer head in a proximal direction directs the hammer head towards the ferrule accepting opening (FIG. 16B and 16C).

Regarding claim 4, Sauer discloses that the second camming surface forms a wall of the hammer head opening and flares outwardly towards the distal end of the tip (FIG. 16A).

Regarding claim 5, Sauer discloses that the first camming surface and the second camming surface abut flushly when the hammer head is at the distal end of the tip (FIG. 16A).

Regarding claim 6, Sauer discloses that the first camming surface does not abut the second camming surface when the hammer head is pulled proximally of the ferrule accepting opening (FIG. 16D).

Regarding claim 7, Sauer discloses that the tip further comprises an aperture (128b) between the distal end and the proximal end of the tip, the cutting edge (144d) located distally of the aperture (FIG 16A).

Regarding claim 8, Sauer discloses that proximal movement of the hammer head within the tip causes the ferrule engaging edge of the hammer head to contact the cutting edge after the hammer head has past the ferrule accepting opening of the tip (FIGS 16A-16F).

Regarding claim 9, Sauer discloses that the tip comprises a distal end outer diameter and a proximal end outer diameter, wherein the outer diameter of the distal end is greater than the outer diameter of the proximal end (FIG 16A).

Regarding claim 10, Sauer discloses a handle assembly having a trigger (116), wherein activation of the trigger draws the hammer head proximally within the tip (Column 14 lines 26-33).

Regarding claim 12, Sauer discloses an adjustment screw within the handle assembly, wherein a length of a central rod connecting the hammer head to the handle assembly is adjustable by the adjustment screw (Column 12 lines 43-65).

Regarding claim 55, Sauer discloses a method of securing suture material using a crimping and cutting device, the method comprising: threading the suture material through a ferrule in the device (FIG 16D suture material 156); moving a hammer head proximally through a tip of the device to crimp the ferrule (FIGS. 16A-16F); continuing to move the hammer head proximally after the ferrule has been crimped entrapping the suture material within the ferrule (FIG. 16E); abutting the hammer head against a cutting edge within the tip (FIGS. 16D-16F), capturing the suture material therebetween; and, applying pressure with the hammer head against the cutting edge until the suture material is cut (FIG. 16E).

Regarding claim 56, Sauer discloses that moving the hammer head proximally comprises squeezing a trigger on a handle assembly of the crimping and cutting device (Column 14 lines 26-33).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 11 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. '289 in view of U.S. Patent No. 5,839,639 to Sauer et al.

Sauer '289 discloses the claimed invention except for the safety button. Sauer '639 teaches that a safety button is provided to prevent premature firing of the anvil assembly (Column 4 lines 27-46 and Column 6 lines 35-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Sauer e'289 with the safety button of Sauer '289 in order to prevent premature firing of the hammer (anvil) element.

Response to Arguments

6. Applicant's arguments filed June 17, 2004 have been fully considered but they are not persuasive.

7. Applicant argues that Sauer et al. '592 and Sauer et al. '289 do not disclose a *generally stationary* surface as the cutting surface. Sauer '592 discloses a pivoting blade (144) that pivots between two points. The blade is limited in its motion and is thus considered to be *generally stationary*. Sauer '289 discloses a blade (cutting edge) that extends forward to the tip (FIG 5). The blade is limited in motion and is thus considered to be generally stationary. The rejections over, Sauer et al. '592 and Sauer et al. '289 are, therefore, deemed proper.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter
Examiner
Art Unit 3731

jrb

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
8/15/04.